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Admitted in NY only " Admitted in TX only

May 31, 2002

Commissioner for Patents Washington, D.C. 20231

Re:

U.S. Patent Application No.: 09/994,425

TARGETED DELIVERY OF GENES ENCODING INTERFERON

Inventor: Henry C. Chiou et al. Filed: November 26, 2001 Our Ref. No.: TTI-143CPCN2

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

- 1. Information Disclosure Statement:
- 2. PTO Form 1449;
- 3. A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on:

May 31 Date

Remillard, Reg. No. 38,872

Respectfully submitted,

LAHIVE & COCKFIELD, LLP

E. Remillard

Registration No. 38,872

Attorney for Applicants





In re the application of: Henry C. Chiou et al.

Group Art Unit:

Serial No.: 09/994,425

Examiner:

Filed: November 26, 2001

For: TARGETED DELIVERY OF GENES

**ENCODING INTERFERON** 

Attorney Docket No.: TTI-143CPCN2

Commissioner for Patents Washington, D.C. 20231

Certificate of First Class Mailing (37 CFR §1.8(a))

I hereby certify that this correspondence is being deposited with the United States Postal

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20231 on the date set forth below.

May 31, 2002

Date of Signature and of Mail Deposit

By:

Jane E. Remillard Registration No. 38,872

Attorney for Applicants

## INFORMATION DISCLOSURE STATEMENT

Dear Sir:

For the Examiner's convenience in reviewing this continuation application, Applicant submits a consolidated PTO Form 1449, listing all references cited during the prosecution of the parent application. The present application is a continuation of U.S. Serial No.09/379,434, filed August 23, 1999 (Atty. Docket No. TTI-143CPCN). All references listed on the enclosed PTO Form 1449 have been previously cited by or submitted to the Office in the prior application, and, in accordance with 37 CFR §1.98(d), copies of the of the references are not enclosed but will be provided upon request.

Serial Number: 09/994,425 Page -2- Filing Date: November 26, 2001

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,

LAHIVE & COCKFIELD, LLP

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Attorney for Applicants

28 State Street Boston, MA 02109 (617) 227-7400

Date: May 31, 2002

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TTI-143CPCN2

09/994,425

Henry C. Chiou et al GROUP

November 26, 2001

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	Ä1	5,166,320	11/92	Wu et al.	530	395	<u> </u>
	A2	5,346,696	09/94	Kim et al.	424	85.4	

## FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	Country	CLASS	SUBCLASS	TRANSLATION	
 A3	WO 92/19749	11/92	PCT		-	YES	NO
A4	WO 92/22310	12/92	PCT				
 A5	WO 92/22635	12/92	PCT				
A6	WO 93/07283	04/93	PCT				
 A7	WO 93/15609	08/93	PCT			,	
A8	WO 94/06922	03/94	PCT				
A9	1 111 159	11/95	China			· 3 · · ·	

OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

	A10	Abstract from the Second Annual Industry Congress on Hepatitis, entitled "Receptor-Mediated Delivery of Therapeutic Agents for Treatment of Chronic HBV Infections", Bartholomew, R.M. (circulated in January, 1996)					
	A11	Baron, S. and F. Dianzani (1994), "The interferons: A biological system with therapeutic potential in viral infections", <i>Antivir. Res.</i> <b>24</b> :97-110					
	A12	Baron, S. et al. (1991), "The Interferons: Mechanisms of Action and Clinical Applications," <i>JAMA</i> <b>266</b> :1375-1383					
	A13	Coll, et al.,"In Vitro Targeting and Specific Transfection of Human Neuroblastoma Cells by chCE7 Antibody-Mediated Gene Transfer", <i>Gene Therapy</i> , Abstract provided by the PCT, Vol. 4 (2), pp. 156-161 (1997);					
	A14	"Drug Facts and Comparisons", 1992 Edition, eds. Olin, B.R. et al., St. Louis, MO, pp. 2445-2460					
	A15	Gewert, D. et al. (1993), "Analysis of Interferon-α2 Sequences in Human Genomic DNA," Journal of Interferon Research 13:227-231					
	A16	Hodgson, C. (1995), "Advances in Vector Systems for Gene Therapy," Exp. Opin. Ther. Patents 5:459-468					
	A17	Miller, N. and Vile, R. (1995), "Targeted Vectors for Gene Therapy," FASEB J. 9:190-199					
-	A18	Mulligan, R. (1993), "The Basic Science of Gene Therapy," Science 260:926-930					
Examin	er	Date Considered					

\*EXAMINER:

Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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		ОТНЕЕ	S (includir	na Author Title	Date, Pertinent Page	s Ftc \				
	B1		•		natic Gene Therapy,"		olaryngol He	ad Neck	Surg.	
		<b>119</b> :1100-1107								
	B2			(1995), "Repo rch on Gene Th	ort and Recommendat	ions of t	he Panel to	Assess th	ne	
	В3				rial of interferon alfa-2	2b alone	and after p	rednisone	)	
					patitus B," New Engla					
	B4				xpression of an Interf					
		M13mp7 and S 79:5455-5459	Subsequen	t Purification wi	on with a Monoclonal Antibody," Proc. Natl. Acad. Sci. USA					
	B5		t least thre	ee human type a	alfa interferons; Struc	ture of a	lfa2, " Scier	ce, 209:1	343-	
		1347	<del></del>			· · · =				
	B6		Wu, C.H. et al. (1989), "Targeting Genes: Delivery and Persistent Expression of a Foreign							
	B7		Gene Driven by Mammalian Regulatory Elements in Vivo", J. Biol. Chem. <b>264</b> :16985-16987  Wu, G.Y. and C.H. Wu (1988), "Receptor-mediated Gene Delivery and Expression in Vivo," The							
		Journal of Biological Chemistry 263:14621-14624								
	B8	Wu, G.Y. and C.H. Wu (1987), "Receptor-mediated <i>in Vitro</i> Gene Transformation by a Soluble DNA Carrier System", <i>J. Biol. Chem.</i> <b>262</b> :4429-4432								
	B9				::4429-4432 ed Gene Delivery <i>in</i> V	/ivo " Th	o lournal o	f Piologia	21	
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